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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,762	06/20/2002	Alexander James Bridges	A0000100-01-SMH	7601

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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,762	BRIDGES ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *59,68,71-76,78-94 and 124* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *59,68,71-76,78-94 and 124* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's amendment and response filed on August 11, 2005 wherein claims 62, 65-67, 69-70, and 77 are cancelled and claims 59, 89-94 and 124 have been amended. Claims 1-58, 60-61, 63-64, 95-123, and 125 are cancelled previously.

Currently, claims 59, 68, 71-76, 78-94 and 124 are pending in this application and under examination on the merits.

Applicant's amendment filed August 11, 2005 with respect to the rejection of claims 59, 62, 65-94 and 124 made under 35 U.S.C. 112 first paragraph for containing new subject matter which was not described in the original specification and claims, of record stated in the Office Action dated June 1, 2005 have been fully considered and found persuasive to remove the rejection since the claims have been amended to remove the new matter of record. Therefore, the said rejection is withdrawn.

Applicant's amendment filed August 11, 2005 that limits the claims to a method of treating chronic pain associated with arthritis, with respect to the rejection made under the judicially created doctrine of obviousness-type double patenting over claims over claims 24, 31, 33 of U.S. Patent No. 6,310,060 of record stated in the Office Action June 1, 2005 have been considered and are found persuasive to remove this particular rejection. Therefore, the said rejection is withdrawn.

The following is new rejection(s) necessitated by Applicant's amendment filed on August 11, 2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 59 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment with respect to the amended claim 59 has been fully considered but is deemed to insert **new matter** into the claims since the specification as originally filed does not provide support for the **subgenus**, with the new proviso limitation in the instant claimed method.

The specification as originally filed merely discloses that the **broad genus** compounds of formula I(B), or specific compounds or species, but fails to disclose the subgenus, with the new proviso.

As noted in MPEP 2163, "a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads", see *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972).

The court of *In re Curtis* held that "a patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single

species when... the evidence indicates ordinary artisans could not predict the operability .....of any other species." (see *In re Curtis* 354 F.3d 1347, 69 USPQ2d 1274, Fed. Cir. 2004).

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 59 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The new proviso limitation in the claim render the claim indefinite. The new proviso are **unclear** as to the recitation "with proviso that either..", whether each proviso applied at once, e.g., when Rc is C_{1-2} alkyl, or how many proviso applied together e.g., when R_c is C_{1-2} alkyl and J is $SOCH_3$, or when R_c is C_{1-2} alkyl and R_1 is H or CH_3, in order to describe or define the subgenus of the formula (I)B. Hence, one of ordinary skill in the art could not ascertain and interpret the subgenus of the formula (I)B encompassed thereby.

Claim 59 recites "R_2". There is insufficient antecedent basis for this limitation since there is not "R_2 " described in the structural formal (I)B and all substituents.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 59 is rejected under 35 U.S.C. 102(b) as being anticipated by Connor et al. (EP 0 316 630 A, of record).

Connor et al. discloses that the active compounds of formula I which read on the instant compounds (see particularly page 5-6, e.g. Example 13 and 18 at page 24-25), being cycloxygenase inhibitors, are useful in pharmaceutical compositions and methods for treating inflammation, **arthritis**, and pain (see abstract, page 4 lines 35-37, page 8 line 40-41, and claims 1-17).

Note that claim 62 herein recites the neuropathic pain is associated with inflammation, arthritis.

Further note that Connor et al. discloses that the effective amount of dexamethasone to be administered is in the range of 0.5 mg to 500 mg/kg/day or 0.5 mg to 50 mg/kg/day (see col.4 lines 15-17), which are within or overlapping with the effective amounts, 0.1-1000 mg/kg per day, preferably 1-300 mg/kg body weight, or

daily dosages 10-5000 mg for an adult subject of normal weight, indicated in Applicant's specification (see page 74 line 29-31 of the specification).

Thus, Connor's method anticipates the claimed method, since Connor's method steps are same as the instant method steps, administering the same compound in the same amount to the same or similar patient population. See Ex parte Novitski, 26 USPQ 2d 1389, 1391 (Bd. Pat. App. & Int. 1993).

Thus, the disclosure of Connor et al. anticipates claim 59.

Claim 59 is rejected under 35 U.S.C. 102(b) as being anticipated by Fujimura et al.: "HYDCOXAYIC ACID DEZIVATIVES" CHEMICAL ABSTRACTS + INDEXES, AMERICAN CHEMICAL SOCIETY. COLUM8US,US, vol. 70, no. 3 20 January 1966 (1969-01-20), or JP 42 024578 A or JP 42019583 B4 (TAKEDA CHEMICAL INDUSTRIAL LTD, 1967, of record).

Fujimura et al. discloses that the active compounds of formula I which read on the instant compounds (see particularly abstract), are useful as analgesics. Thus, these compounds are useful in pharmaceutical compositions and methods for treating chronic pain associated with arthritis (see abstract).

Fujimura et al. was silent regarding that the same compound herein is a MEK inhibitor, However, "a MEK inhibitor" is merely an inherent property of the known compound of Fujimura et al., or the mechanism of action of the known compound of Fujimura et al., adding nothing to the patentability of the claims, so long as the same compound is taught as analgesics.

Thus, the disclosure of FUJIMURA H et al. anticipates claims 59.

Claim 59 is rejected under 35 U.S.C. 102(b) as being anticipated by Morkhort (of record).

Morkhort discloses that the active compounds therein which read on the instant compounds (see particularly abstract), are useful as analgesics. Thus, these compounds are useful in pharmaceutical compositions and methods for treating chronic pain associated with arthritis (see abstract).

Thus, the disclosure of Morkhort anticipates claims 59.

Claims 59 and 78 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirano Hiroshi et al. (JP 42019583 B4, TAKEDA CHEMICAL INDUSTRIAL LTD, 1967 of record).

Hirano Hiroshi et al. discloses that the active compounds therein which read on the instant compounds (see particularly abstract), are useful as analgesics. Thus, these compounds are useful in pharmaceutical compositions and methods for treating treating chronic pain associated with arthritis (see abstract).

Thus, the disclosure of Hirano Hiroshi et al. anticipates claims 59..

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 59, 68, 71-76, 78-94 and 124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barrett et al. (WO 99/01421, PTO-1449 submitted May 16, 2003) in view of Walker et al. BRITISH JOURNAL OF CLINICAL PHARMACOLOGY, (1993 Nov) 36 (5) 417-25, of record).

Barrett et al. discloses that the active compounds of formula I which read on the instant compounds, have covered the instant compounds, or are structurally substantially similar to the instant compounds (see particularly Formula II, III and IIIa at page 5-6, and e.g. Example 212), being MEK inhibitors, are useful in pharmaceutical compositions and methods for treating inflammation (see abstract, page 1-3, and claims 1-34).

Barrett et al. do not expressly disclose the employment of the particular MEK inhibitors therein, in a method of treating chronic pain associated with arthritis.

Walker et al. teaches that pain is well-known to be associated with inflammation. See "abstract" in particular. Arthritis is a well-known inflammation.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular MEK inhibitors of Barrett et al. in methods of treating chronic pain associated with arthritis.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular MEK inhibitors of Barrett et al. in methods

of treating chronic pain associated with arthritis, because particular MEK inhibitors of Barrett et al. is known to be useful in methods of inflammation according to Barrett et al. Pain is well-known to be associated with inflammation and arthritis is a well-known inflammation.

Further, some of the instant compounds read on the compounds of Barrett et al. while other the instant compounds have been covered by the formula of Barrett et al., or are structurally substantially similar to. As noted in MPEP 2144, "If such a species or subgenus is structurally similar to that claimed, its disclosure may motivate one of ordinary skill in the art to choose the claimed species or subgenus from the genus, based on the reasonable expectation that structurally similar species usually have similar properties. See, e.g., Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also Deuel, 51 F.3d at 1558, 34 USPQ2d at 1214. The utility of such properties will normally provide some motivation to make the claimed species or subgenus. Id. Dillon, 919 F.2d at 697, 16 USPQ2d at 1904-05 (and cases cited therein). If the claimed invention and the structurally similar prior art species share any useful property, that will generally be sufficient to motivate an artisan of ordinary skill to make the claimed species, In fact, similar properties may normally be presumed when compounds are very close in structure. Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also In re Grabiak, 769 F.2d 729, 731, 226 USPQ 870, 871 (Fed. Cir. 1985) ("When chemical compounds have very close' structural similarities and similar utilities, without more a prima facie case may be made."). Thus, evidence of similar properties or evidence of any useful properties disclosed in the prior art that would be expected to be

shared by the claimed invention weighs in favor of a conclusion that the claimed invention would have been obvious. Dillon, 919 F.2d at 697-98, 16 USPQ2d at 1905; In re Wilder, 563 F.2d 457, 461, 195 USPQ 426, 430 (CCPA 1977); In re Linter, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

Therefore, one of ordinary skill in the art would have reasonably expected that the particular MEK inhibitors herein, would have beneficial therapeutic effects and usefulness in methods of treating chronic pain caused by inflammation such as arthritis.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's arguments filed on August 11, 2005 with respect to the prior art rejections of record in the previous Office Action June 1, 2005 have been considered but are moot in view of the new ground(s) of rejection above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 59, 68, 71-76, 78-94 and 124 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34-35, 41, 43 of U.S. Patent No. 6,506,798

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a method of treating a mammal suffering from osteoarthritis, rheumatoid arthritis, diabetes or cancer comprising administering the same compound or substantially same or similar compound as instantly claimed.

The claims herein are directed to in a method of treating chronic pain associated with arthritis.

Thus, the method in the instant application is seen to be obvious over the claims 34-35, 41, 43 of U.S. Patent No. 6,506,798.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
September 30, 2005